



Drive-Through Model for Anticoagulation Clinics During the COVID-19 Pandemic

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Abstract

The coronavirus disease of 2019 (COVID-19) has posed a major challenge for providers and patients. A large number of patients with atrial fibrillation, venous thromboembolism, or valvular heart disease are chronically anticoagulated with vitamin K antagonists and rely on frequent follow ups at anticoagulation clinics for management of their anticoagulation therapy. The need for isolation during COVID-19 pandemic can potentially limit access to health care including anticoagulation clinics and directly affect the care of patients on chronic anticoagulation. Therefore, we created a drive-through clinic to bridge the gap of continuation of care and preservation of social distancing precautions. In this manuscript, we report the steps in implementing such initiative which can be applied to other clinics during a pandemic.

Keywords

COVID-19, anticoagulation, drive-through clinic

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Introduction

Pandemics greatly increase morbidity and mortality over a wide geographic area and cause significant economic, social, and political disruption. While the evidence suggests that the frequency and intensity of these pandemics are increasing, most recent H1N1 and Ebola outbreaks taught us that “The world is ill prepared to respond to a severe influenza pandemic or to any similar global, sustained and threatening public health emergency.”¹⁻⁴ Thus, to minimize the number of people affected by a disaster, the response by the public health agencies must be fast and efficient.³

The coronavirus disease of 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV2). Given the rapid spread of this virus with consequences on an international scale, the World Health Organization (WHO) declared the novel COVID-19 outbreak a global pandemic on March 11th 2020.⁵ Besides acute respiratory syndromes, COVID-19 also have significant impacts on cardiovascular system. Preexisting cardiovascular disease (CVD) predispose patients to more severe COVID-19 infection and is associated with higher risk of adverse outcomes,⁶ which highlights the importance of social distancing in order to decrease the risk of exposure and possibility of acquiring the infection in this patient population.

Despite the advent of direct oral anticoagulants (DOACs), a large number of patients with atrial fibrillation, venous

thromboembolism, or valvular heart disease are chronically anticoagulated with vitamin K antagonists (VKA). VKAs are commonly used for prevention and treatment of thromboembolic events in a variety of CVD. The efficacy and safety of VKA are anchored on adequate monitoring, in order to reduce the likelihood of life-threatening hemorrhagic or thromboembolic events.⁷ While previous studies have shown that pharmacist or nurse-led point-of-care (POC) International Normalized Ratio (INR) clinics improve control of anticoagulation therapy,⁸⁻¹⁰ this demands frequent healthcare visits in shared spaces. The need for isolation during

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Table 1. Challenges of Anticoagulation Clinic During COVID-19 Pandemic.

Forces for change	Forces against change
Fear of patients and staff associated with COVID 19	Scheduling issues
Need for social distancing	Patient access to transportation
Patient desire for limiting exposure to COVID 19	Need to train staff and patients on new workflow
Staff driving necessary change to adapt to pandemic	Patients and providers want for in person visits
Change in CMS billing rules and requirements for telemedicine visits	Resource constraints
Safety of staff (preventing exposure to COVID 19)	Staff pushback to change- new workflow and loss of in person interaction
Accreditation changes for pharmacists to use telemedicine	Insurance billing and coding issues
Patient appetite for drive-through convenience	Telemedicine stigma

COVID-19 pandemic can potentially limit access to health care including anticoagulation clinics; moreover, an international expert panel document advocated the creation of methods to facilitate social distancing among patients who need INR monitoring.¹¹

For the past 20 years, NorthShore University Health System (Evanston, IL) anticoagulation clinics have developed a structured care program for patients taking VKA, who are managed by a multidisciplinary, collaborative team consisting of the patient's primary care physician or specialist, a clinical pharmacist, and nurses. The 3 NorthShore anticoagulation clinics care for over 2000 patients in the northwest suburbs of Cook County, IL, with almost 37,000 visits annually (more than 3,000 patients on a monthly). Clinical pharmacists are responsible for titrating and monitoring VKA therapy in a systematic method according to system-approved clinical guidelines.

As part of a quality improvement project in response to the COVID-19 pandemic, we designed a drive-through pharmacist-led POC anticoagulation clinic at NorthShore in order to comply with social isolation rules while providing standard care to patients on chronic anticoagulation.

Method

COVID-19 pandemic posed a significant and worrisome decrease in patients' attendance at NorthShore anticoagulation clinics which required an evaluation of our response to this crisis. In order to better understand the situation, an emergency virtual meeting was held to assess patients and providers' needs besides potential obstacles to achieve quality care to this population (Table 1). After careful consideration of challenges and available resources, we decided to implement a drive-through anticoagulation clinic. The objective of this manuscript is to share the multi-step implementation process and quality metrics we developed.

Steps to Implement Drive-Through Clinic

With the intention of reducing risk of virus exposure, hospitals and clinics are taking precautions to limit non-urgent visits, maintain social distancing practices, as well as reduce office hours which can create a significant challenge for patients on chronic anticoagulation. In order to provide the best possible care for our patients while adapting to the new environment set by the pandemic, the concept of the drive-through clinic was created by our pharmacy and vascular medicine departments

who manage patients on a daily basis at the anticoagulation clinics.

The urgency of the issue consisted in continuing to provide safe and consistent care to patients on chronic anticoagulation while limiting patient and staff exposure during the pandemic. This vision was presented to a thrombosis-dedicated multidisciplinary meeting with NorthShore administration. NorthShore leadership evaluated the urgency of the matter and determined the drive-through clinic as a safe and practical alternative for both patients and providers.

A core team was created including pharmacists and vascular medicine physicians who designed a detailed implementation plan. A step wise plan of daily procedures of this drive-through clinic was outlined by the core team. Afterward, other pharmacy providers were enlisted to get trained on how to perform the test, appropriate donning and doffing of Personal Protective Equipment (PPE), and other steps of the drive-through visit. We obtained permission from our administration to redirect our staff in enabling this clinic's daily procedures. After the implementation of the drive-through clinic, the initial data and metrics were sent to the core team for further evaluation. Virtual conferences took place to provide feedback on the initial data and further steps. The coverage was expanded not only to patients previously enrolled in our anticoagulation clinic, but also to patients on VKA who were not previously managed by our team. The initial drive-through clinic operation results were re-evaluated by the core team, and the intervention was successful. This model is currently being applied to other clinics including ophthalmology for measurement of intraocular pressure and diabetes clinics for measurement of hemoglobin A1c (Figure 1).

Materials, Safety and Infection Control

The drive-through POC anticoagulation clinic site is situated at one of the entrances to the hospital ambulatory care center. This site provides access for patients in cars, but also shelter for clinical pharmacists, supplies, and equipment. INR monitoring is performed using the RocheTM CoaguChek[®] XS Plus POC device.¹² The drive-through site utilizes 2 POC devices during hours of operation with additional devices available as backup in case of device failure. Devices are cleaned daily and when visibly soiled per manufacturer and organizational infection control policies. Quality control is also performed on the devices in the clinic based on manufacturer and organizational

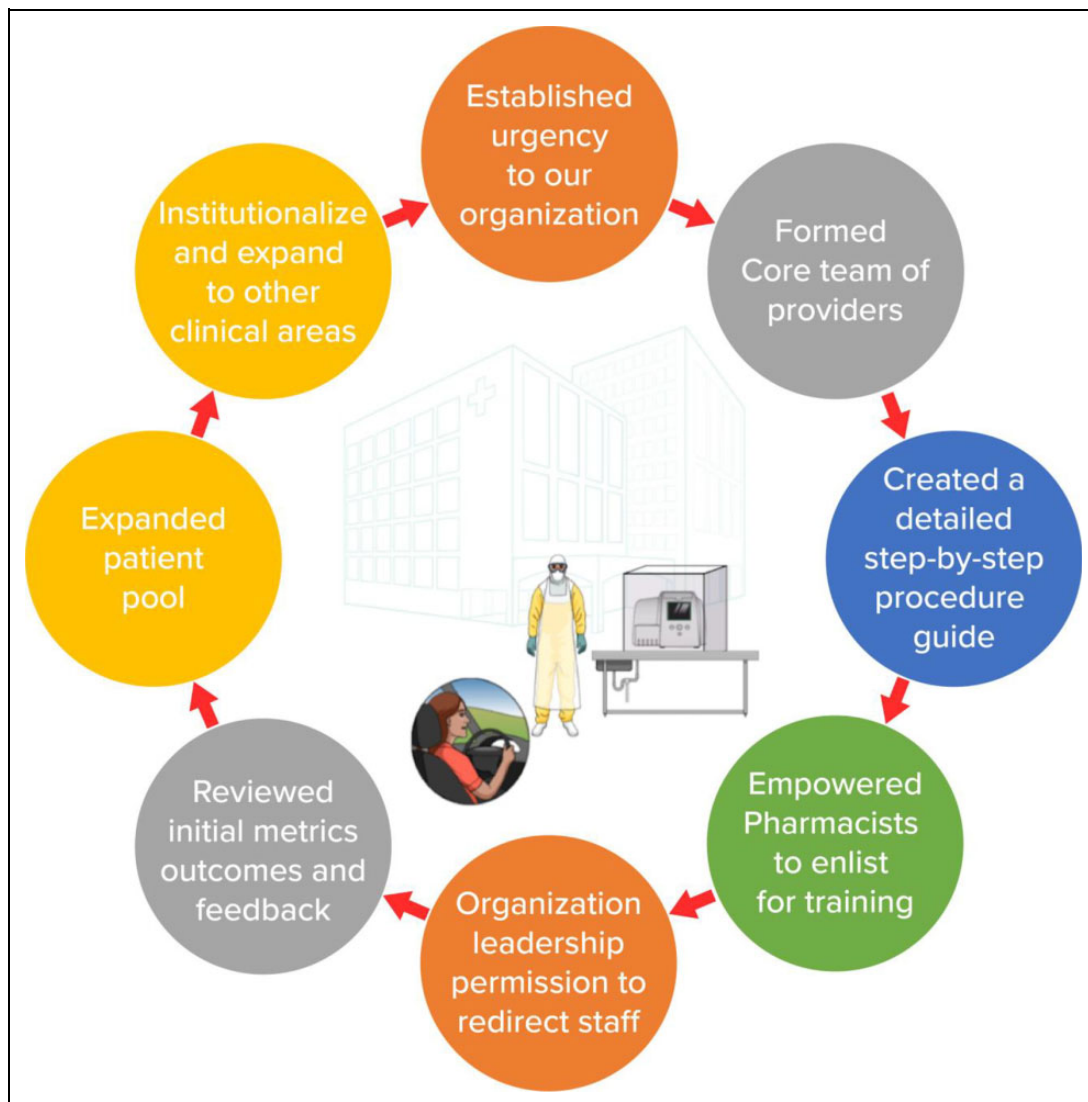


Figure 1. Drive through clinic: stepwise process for drive through clinic implementation.

recommendations. Appropriate environmental conditions were taken into consideration and the POC devices and test strips are maintained in a temperature-controlled area. Testing supplies such as gloves, alcohol pads, test strips, lancets, gauze, bandages, and transfer pipettes are readily accessible. A biohazard sharps container is used for safe disposal of lancets, pipettes, and test strips. Once the test results were available, they were entered in the patient's electronic medical record (EMR) via a computer localized in the vestibule area.

To ensure patient and staff safety, the concept of the drive-through anticoagulation clinic was discussed in detail with institution's infection control and life-safety team. Given the limited amount of time that pharmacists were spending with each drive-through patient, the visits were considered low-risk exposure for providers and patients. Higher risk patients (including patients with a positive test for COVID-19 or recent hospitalization) were screened via phone before coming for their drive-through appointment. If the patient was symptomatic, they were

recommended to stay home. If asymptomatic, they were provided with a surgical mask before their test administration.

Providers were required to wear PPE such as gloves, masks, and goggles for each patient encounter. These supplies were accessible in the vestibule area. The exposure to complete the POC INR test from patient drive up to patient exit took approximately 3 minutes per patient. Careful measures for hand hygiene were taken between each patient and providers had access to disinfecting hand sanitizer and sink for hand-washing.

Screening and Scheduling

All patients registered at NorthShore anticoagulation clinics were called to notify them of the drive-through POC anticoagulation clinic. They were initially screened regarding possible COVID-19 exposure and related symptoms. Appointment slots were scheduled for the drive-through via phone encounters. Four patients were scheduled at every 15 minutes interval from

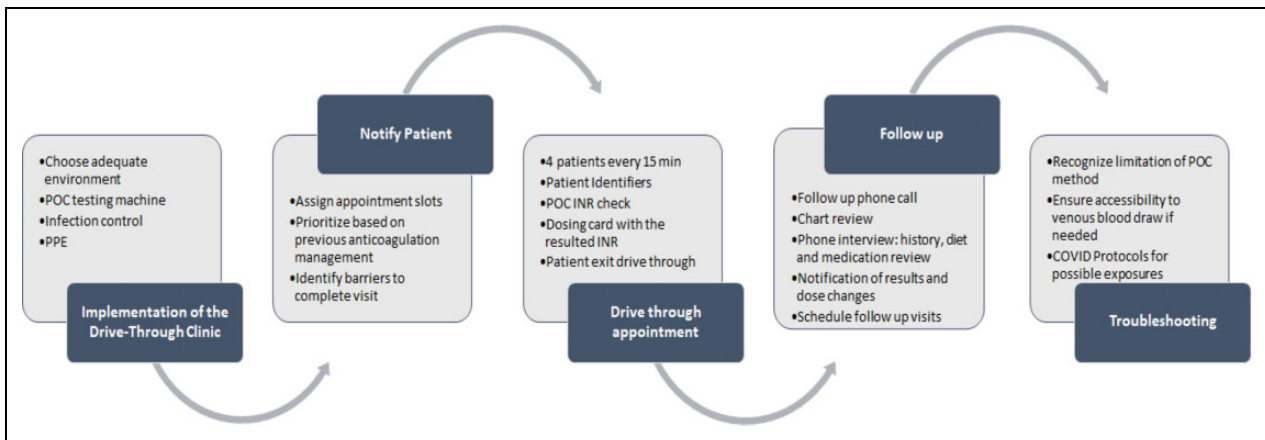


Figure 2. Drive through clinic structure. COVID: coronavirus disease 2019, INR: international normalized ratio, POC: point of care, PPE: personal protective equipment, INR: international normalized ratio.

7:30 am until 4:00 pm, Monday through Friday. There were a 30 minutes lunch and another 15 minutes breaks.

Drive-Through Clinic

Most patients drove through the clinic, although there were patients who utilized public transportation and walked through. Patients were advised to approach the drive-through site at the time of their scheduled appointment only. Patients pulled up to the clinic site and were asked to turn off their engines. Patient identifiers (first and last name, date of birth) were confirmed and consent for care forms were verified and completed if missing. Then, a POC INR check was performed and patient was provided with an appointment and dosing card that contained the resulted INR. Prior to exit from the drive-through, patient was informed about a same-day telephone call regarding dosing instructions and scheduling of the next appointment.

After each clinic visit, the clinical pharmacist initiated a telephone encounter in the EMR during which: patient's name and date of birth verified, EMR reviewed, and patient interviewed which included but was not limited to history, diet and medication changes, adherence to treatment and review of related side effects (bleeding, bruising, etc). Patient was notified of the INR result and a dosing plan was presented. The patient was asked to document the VKA dose on their appointment and dosing card, and teach-back method was used to confirm patient's understanding. The follow-up appointments were scheduled during this telephone visit. Patient was requested to notify the clinic in advance with any new symptoms or if tested for COVID-19. A summary of the drive through model steps is illustrated in Figure 2.

Troubleshooting

Initial troubleshooting elements included the POC device, hand hygiene, and exposure. The POC INR device and test strips require a specific environmental temperature for its operation. On the first day, the POC INR device was exposed to colder temperatures and stopped working. Subsequently, the POC

device resided within a temperature-controlled vestibule adjacent to the drive-through site and samples were taken to the device in the vestibule. The availability of a sink and sharps container were also essential for the execution of the drive-through method. A sharps container was brought to the site and a sink in the adjacent building was accessible through a door.

The INR POC device also has limitations of use which includes INR >4.5, unfractionated heparin concentrations, low molecular weight heparin concentrations, fondaparinux concentrations, presence of antiphospholipid antibodies, hematocrit ranges <25% and >55%, bilirubin >30mg/dL, and triglycerides >500mg/dL. For these circumstances, a venous blood draw is recommended. Although the outpatient laboratory at the drive-through testing site hospital was closed, drive-through clinic could reach to the main lab staff to perform a venous blood test if it was needed.

While the building entrance in which the pharmacists store supplies, equipment, and take shelter is temporarily closed for patients, visitors, and employees, proper emergency exit pathways were carefully reviewed by the organization's life-safety department. The organization's public safety and public relations departments assisted in placement of signs to avoid traffic congestion and accidents at the clinic site. For a small number of patients who walk up to the clinic site, the pharmacists perform the same workflow for these patients safely standing on a walkway.

While screening measures were taken to avoid COVID-19 exposure, there were several occasions where patients had positive COVID-19 tests after their drive-through clinic encounter. Employee who were exposed during these encounters were determined and requested to complete a questionnaire at our COVID-19 internal website. The infectious disease experts reviewed each questionnaire and contacted the healthcare worker and recommended further steps including returning to work or quarantine.

Issues related to billing for the services were discussed in detail with the billing department. Collaboration with institution billing department is encouraged as regional changes are implemented.

Quality Improvement Project

We are currently in the process of obtaining institutional IRB for a qualitative improvement project in order to evaluate the impact of our drive-through model in patient care. A survey is being created by our pharmacy department. By using a quick response (QR) code, patients can utilize their cell phones to complete an anonymous online survey. The time required for the survey is approximately 5 minutes. Patients will be able to complete the survey while waiting in their cars during the visit. Authors will analyze the data to assess the impact of the drive-through model in patient care and satisfaction during the COVID-19 pandemic.

Discussion and Future Directions

In a multi-step approach engaging multiple departments in our institution, we implemented a successful drive-through anticoagulation clinic with the goal of facilitating social distancing while assuring anticoagulation therapy safety.

The COVID-19 pandemic posed a challenge for the management of patients on VKAs that can potentially result in multiple complications including strokes if sub-therapeutic, or bleeding in case of supra-therapeutic INR. Our goal was to reduce patient exposure to a high-risk setting like the hospital while meeting their needs for being managed by the anticoagulation clinic. Considering previous successful experiences with drive-through vaccination clinics,³ we designed a drive-through POC anticoagulation clinic which was successfully executed within less than 2 weeks of announcement of the COVID-19 as a pandemic. By the end of the first month from clinic implementation, all clinic patients were notified and screened for their appointments and close to 2600 INR testing visits with an average of 90 patients per day were performed.

Our organization is the first in this geographic area to create such model for anticoagulation clinics with the goal of serving needs of our patients in a safe method despite potential financial losses.

Our next goal is to survey patient satisfaction along with the challenges patient and staff encountered. Incorporating telemedicine rather than phone calls to add the visual aspect to the follow up visits is another field that we are actively exploring. We believe that drive-through method can be applied to other clinics which use POC monitoring tests such as diabetes and ophthalmology clinics.

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