Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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RESEARCH ARTICLE

Evaluation of a pharmacist-led drive-up anticoagulation clinic during the coronavirus 2019 pandemic

Erin Sherwin, Margaret Schaefer, Mark Huffmyer, Kristina Naseman, George A. Davis, Aric Schadler, Savannah Fraley, Brittany Smith*

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ABSTRACT

Background: The University of Kentucky HealthCare Anticoagulation Clinic at the Gill Heart and Vascular Institute in Lexington, Kentucky, designed and implemented a drive-up clinic for warfarin management with the goal to minimize person-to-person exposure during the coronavirus disease 2019 (COVID-19) pandemic.

Objective: The purpose of this study was to evaluate the effect on warfarin management in a pharmacist-led anticoagulation service when transitioned from an in-person clinic to a drive-up clinic during the COVID-19 pandemic.

Methods: This is a retrospective observational cohort study of 68 patients seen in the University of Kentucky HealthCare Anticoagulation Clinic on warfarin therapy for any indication. Patients were included if they had scheduled visits at least 3 times in the period 6 months before, during, and after the initiation of the drive-up clinic. The primary outcome is the difference in time in therapeutic range (TTR) before and during the drive-up clinic.

Results: The difference between the mean TTR in period 1 (69.1% ± 23.2%) and period 2 (69.6% ± 19.2%) was not statistically significant ($P = 0.882$). The mean TTR in period 3 (70.5% ± 20.8%) did not differ in statistical significance from either period 1 ($P = 0.688$) or period 2 ($P = 0.746$). Safety outcomes including reported bleeding events and emergency department visits or hospital admissions for bleeding or thrombotic events were consistently low across each period.

Conclusion: The results of this study illustrate that a drive-up clinic for warfarin management may be a reasonable alternative approach to providing care for outpatient anticoagulant management and may support nontraditional clinic models for long-term management of anticoagulation and other chronic disease states.

Background

Anticoagulation with warfarin requires frequent laboratory monitoring and follow-up to maintain a therapeutic international normalized ratio (INR) and to prevent adverse patient outcomes such as bleeding or thrombosis.[1] A patient's target INR range depends on several factors, but especially on the medical indication for warfarin.[1] Time in therapeutic range (TTR) is a metric used to reflect the quality of anticoagulation on warfarin, with TTR less than 60% typically being associated with worse clinical outcomes related to bleeding and thrombosis.[2,3] Clinical pharmacists have illustrated the ability to provide safe and effective warfarin management in pharmacist-led anticoagulation clinics; thus, chronic warfarin therapy is often managed by pharmacists in the United States.[4] The coronavirus disease 2019 (COVID-19) pandemic challenged health care systems to find new modes of care to mitigate the spread of the disease, ensure the safety of patients and staff, and continue necessary medication management. For patients on warfarin, many of whom are of older age or living with multiple comorbidities, the need for frequent in-person visits for therapy management had the potential to

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* **Correspondence:** Brittany Smith, PharmD, University of Kentucky HealthCare, 800 Rose St., Lexington, KY 40536.
E-mail address: brsmith12@uky.edu (B. Smith).

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Key Points

Background:

- Many health care institutions developed innovative care models to adhere to social distancing requirements during the coronavirus 2019 pandemic, including drive-up and drive-through options to monitor anticoagulation for patients on warfarin.
- Previous literature over the past 2 years includes studies of varying size with different descriptions of how these drive-up clinics were designed and have demonstrated varying results regarding effect on time in therapeutic range (TTR) and other clinical and logistical outcomes.

Findings:

- We designed a robust study with enough statistical power to evaluate the difference in TTR before, during, and after the implementation of a drive-up clinic.
- The results of this study support the integration of a drive-up clinic as a feasible way to deliver care. Our institution has used these results to support the implementation of long-term drive-up point-of-care testing services beyond anticoagulation.

increase the risk of exposure to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

In the spring of 2020, the Anticoagulation Forum (AC Forum) released guidance for "frequently asked questions," which they later published as recommendations, to help providers and clinic staff optimize anticoagulation management during COVID-19.[5] These recommendations included transitioning eligible candidates from warfarin to direct oral anticoagulants (DOACs), which require less frequent monitoring than warfarin; using telemedicine follow-ups with home monitoring instead of in-person clinic visits; extending the time between appointments to check point-of-care test (POCT) INRs; employing the use of facemasks, social distancing, and hand hygiene; and using "drive-up" POCT INR monitoring.[5]

Since the onset of the pandemic in March 2020, several studies conducted at a variety of institutions have been published that describe and evaluate the innovative changes made for anticoagulation management.[6-18] Transitioning in-person care to drive-up clinics, where patients could receive care while socially distanced in their vehicle, was a commonly reported intervention shown to sustain a TTR above the threshold for adequate anticoagulation.[7-11,13] One small study in pediatric patients demonstrated a statistically significant improvement in TTR with a drive-up clinic.[10] Several of these studies also reported high patient satisfaction with this clinic model.[8-10,14]

The University of Kentucky HealthCare Anticoagulation Clinic at the Gill Heart and Vascular Institute in Lexington, Kentucky (UK HealthCare Anticoagulation Clinic), implemented each of the AC Forum recommendations in 2020, including a drive-up POCT INR clinic to replace in-person clinic appointments.

Objective

The purpose of this study was to evaluate the efficacy and safety of warfarin management in a pharmacist-led anticoagulation service when transitioned from an in-person clinic (the "traditional model") to a drive-up clinic during the COVID-19 pandemic.

Methods

Study design

This is a retrospective observational cohort study, approved by the University of Kentucky Institutional Review Board under expedited review. The study period encompasses an 18-month period: the traditional anticoagulation model in the 6 months before the implementation of the drive-up clinic (September 30, 2019, to April 10, 2020, defined as period 1), 6 months during the drive-up clinic (April 13, 2020, to October 23, 2020, defined as period 2), and 6 months after closing the drive-up clinic (October 26, 2020, to May 7, 2021, defined as period 3).

Traditional clinic model

The UK HealthCare Anticoagulation Clinic sees approximately 200 patients monthly at on-site appointments for warfarin management. Patients seen in this clinic include those with atrial fibrillation or venous thromboembolism who are not ideal candidates for DOACs because of indication (e.g., presence of a mechanical heart valve or genetic or congenital conditions that preclude anticoagulation with DOACs), presence of contraindications, patient affordability, or patient preference. The clinic is managed by a team of clinical ambulatory care pharmacists and a medical assistant working in collaboration with supervising providers. The pharmacists are credentialed and privileged by the health system and thus can order anticoagulant medications and appropriate laboratory tests for monitoring. Patients are referred to the anticoagulation clinic via an electronic referral form and must have a managing or supervising UK HealthCare provider who sees the patient at least once a year.

Before the COVID-19 pandemic, the UK HealthCare Anticoagulation Clinic managed chronic warfarin therapy through 20-minute face-to-face clinic visits at the UK HealthCare Gill Heart and Vascular Institute, which has 2 separate locations: one in the UK HealthCare Albert B. Chandler Hospital and one in the Good Samaritan Medical Office Building, approximately 1 mile from the hospital. During a face-to-face visit, the medical assistant directs patients to a clinic room and obtains a POCT INR using the Roche CoaguChek XS Meter (https://diagnostics.roche.com/us/en/products/instruments/coaguchek-xs-ins-804.html#productSpecs). The pharmacist enters the room once the patient is ready to discuss the INR, obtain a history for factors that may influence their INR, and communicate the anticoagulation care plan. For some patients, the clinic used remote monitoring strategies, which included obtaining POCT INRs from either a monitor used by the patient at home or venipuncture at laboratories within and outside the UK system. Therapy was assessed and discussed over the telephone for the

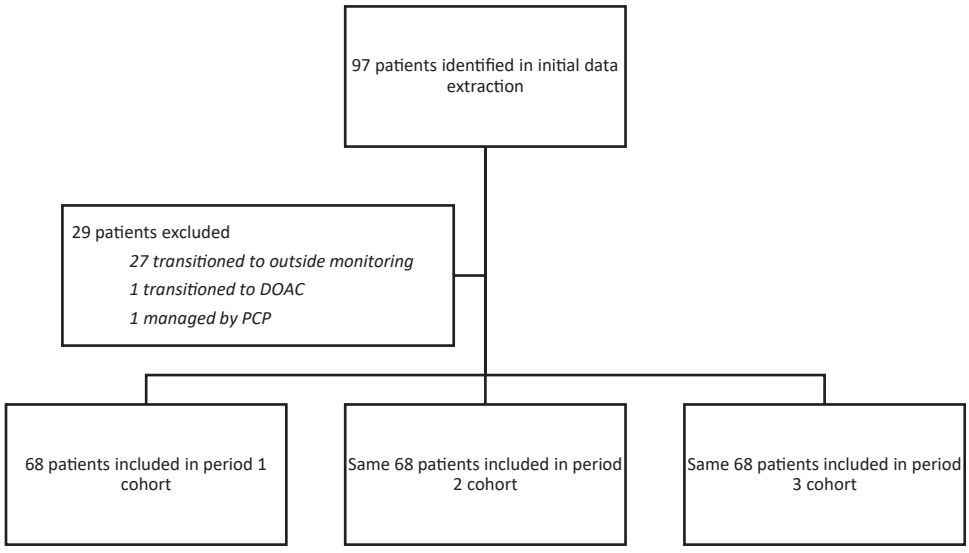

Figure 1. Patient selection. Abbreviations used: DOAC, direct oral anticoagulant; PCP, primary care provider.

patients using these remote monitoring strategies. These home monitoring patients were excluded from the study.

Drive-up clinic model

Patients seen in period 2 were automatically transitioned to the drive-up model at its inception. The drive-up clinic model consisted of 20-minute scheduled visits in which the patient presented to a designated parking spot outside the Good Samaritan Medical Office Building. The patient presented in their vehicle and was screened for COVID-19 symptoms using the standard UK HealthCare questionnaire via telephone by a medical assistant. With appropriate personal protective equipment (PPE), the medical assistant presented outside the patient's personal vehicle to obtain a POCT INR. The medical assistant provided the result to the clinical pharmacist who remained within the clinic and contacted the patient via telephone to discuss the INR, interview the patient regarding factors that may influence their INR, and communicate the anticoagulation care plan. Alternatively, if the patient could not be contacted via telephone—such as patients who requested an interpreter for languages other than English, preferred written instructions, or did not have a phone—the clinical pharmacist presented to the patient's personal vehicle with appropriate PPE to discuss and communicate the plan. The drive-up clinic model lasted from April 13, 2020, to October 23, 2020, after which patients were transitioned back to the traditional face-to-face model. The drive-up clinic closed in October because of dropping temperatures from fall and winter weather (the manufacturer recommends against using the CoaguChek XS Meter at temperatures below 59°F), as well as the institution-wide transition back to in-person clinic appointments at that time.[19]

Study population

The study population consisted of patients who were seen in person before the COVID-19 pandemic who were transitioned to the drive-up clinic in period 2 before returning to face-to-face visits in period 3. Patients were included if they were 18-99 years of age on chronic warfarin therapy seen by a clinical pharmacist for at least 3 visits in each period (for a minimum of 9 visits total during the study period). Visits where INR was evaluated via POCT during the visit were included, as well as visits that included venipuncture INR results when indicated according to the clinic's protocol (POCT INR > 4.0 or based on clinical judgment). Patients who had a visit with another UK provider that obtained frequent laboratory tests at UK HealthCare, including venipuncture INR, were contacted via telephone by the anticoagulation pharmacist to discuss INR results in lieu of a standard face-to-face point-of-care visit, which allowed for the most convenient care to the patient. These patients were included because they attended most of their visits via either the traditional model (period 1 or period 3) or the drive-up model (period 2) and were evaluated on POCT INR at these visits. Similarly, patients occasionally presented to the UK Emergency Department for concerns unrelated to anticoagulation, and INRs obtained at those visits were addressed via telephone by the anticoagulation pharmacist if the patient was not admitted. Each INR addressed in a clinic visit or via telephone was included in the calculation of TTR for the patients included.

Patients were excluded if they used home monitoring or external laboratory monitoring, unless for reasons previously specified; if their warfarin therapy was managed by a provider outside the anticoagulation clinic; or if they were transitioned to any DOAC (rivaroxaban, apixaban, dabigatran, or edoxaban) at any point during the study period.

Data collection

Using the defined inclusion criteria, the UK Center for Clinical and Translational Sciences (CCTS) obtained patient information for inclusion from the electronic medical record (EMR). This information included demographics, POCT and venipuncture INR results, visit details (e.g., dates and locations), warfarin indications and ICD-10 diagnosis codes (included in the Supplemental Appendix), and active

Table 1
Baseline demographics

Baseline characteristics	
Demographic characteristics	Values
Age, y	60 ± 16
Male, n (%)	42 (61.8)
Female, n (%)	26 (38.2)
Weight, kg	101.8 ± 34.9
BMI, kg/m^2	34.4 ± 11.0
Race, white, n (%)	55 (80.9)
Race, African American, n (%)	13 (19.1)
Ethnicity, non-Hispanic, n (%)	62 (91.2)
Ethnicity, Hispanic, n (%)	5 (7.4)
Comorbidity, n (%)	
Hypertension	50 (73.5)
Heart disease	64 (94.1)
Heart failure	20 (29.4)
Type 2 diabetes mellitus	15 (22.1)
Stroke	2 (2.9)
Obesity	22 (32.4)
Cancer	3 (4.4)
Indications for anticoagulation, n (%)	
Atrial fibrillation/atrial flutter	38 (55.9)
Mean $CHADS_2$-VASC score	3.97 ± 1.87
Venous thromboembolism	22 (32.4)
Prosthetic or mechanical valve	12 (17.6)
Left ventricular thrombus	2 (2.9)
Antiphospholipid syndrome	3 (4.4)
Lupus anticoagulant disorder	3 (4.4)
Protein C/S deficiency	1 (1.5)
Factor V Leiden	3 (4.4)
Hemophilia A/factor VIII deficiency	0 (0.0)
Factor II deficiency	1 (1.5)
Antithrombin deficiency	1 (1.5)
Prothrombin gene mutation	0 (0.0)
Pulmonary hypertension	6 (8.8)
INR goal range, n (%)	
2.0–3.0	61 (89.7)
2.5–3.5	7 (10.3)

Abbreviations used: BMI, body mass index; INR, international normalized ratio.
Note: Plus-minus values are mean ± SD.

medications. These data were verified by a manual cross-check of 10 patients in the EMR for quality assurance before initiating chart review. Adherence to a consistent diet, adherence to warfarin regimens, and patient- and provider-reported minor bleeding events (e.g., nosebleeds, blood in stool or urine, and excessive bruising) were collected via manual chart review by a pharmacy resident and a student pharmacist using a secure data collection form in REDCap (https://projectredcap.org/software/; included in the Supplemental Appendix). The data collection form was tested on 5 patients to assess for adjustments before initiating chart review. For patients with atrial fibrillation or atrial flutter, a $CHADS_2$-VASC score for stroke risk from the patient's first visit in the first period was collected given that it was documented by the pharmacist in the encounter. HAS-BLED scores for major bleeding risk were not reported because of the inability to retrospectively evaluate weekly alcohol use and vitals (to assess for uncontrolled hypertension).

Using POCT INR results, a formula in Microsoft Excel (https://www.microsoft.com/en-us/microsoft-365/excel) calculated the TTR using the Rosendaal method (number of days in range divided by total monitored days) and the time in range (TIR) (number of in-range visits divided by total number of visits) for each patient in each period.[20,21]

Statistical analysis

The power and sample size analysis were completed using nQuery 9.1 (https://www.statsols.com/nquery/sample-size-software-options; https://www.statsols.com/hubfs/Resources_/nQuery-Manuals/nQuery-Advanced-User-Manual/nQuery9Manual_9.1.1.0.pdf), showing that a sample size of at least 62 pairs was needed assuming 80% power for an equivalence *t* test with *P* value less than 0.05 representing statistical significance. Data were analyzed using IBM SPSS (https://www.ibm.com/docs/en/SSLVMB_27.0.0/pdf/en/IBM_SPSS_Statistics_Core_System_User_Guide.pdf) Statistics Software version 27. Descriptive statistics were used to evaluate baseline demographics, emergency department visits, and hospital admissions. A matched paired *t* test was used to analyze the primary outcome (difference in TTR in period 1 and period 2), difference in TTR and TIR in each period, time between visits, number of visits, percent of patient-reported adherence to warfarin regimen, percent of patient-reported change in diet, and percent of INRs out of the range of 1.5-4.5. A related-samples Wilcoxon signed-rank test was used to evaluate percent of visits with patient- or provider-reported bleeding events.

Results

The initial CCTS data extraction identified 97 patients who met the inclusion criteria. Of those patients, 27 were excluded because they were transitioned to remote home or outside lab monitoring during the study period. One patient was excluded for being transitioned to a DOAC (rivaroxaban) for several months during the study, and 1 patient was excluded because of being managed by her primary care provider for the majority of period 1. This left 68 patients included in the final analysis (Figure 1).

Of the 68 patients included in the final analysis, 42 (61.8%) were male, 55 (80.9%) identified as white, and 13 (19.1%) identified as African American. The most common indication for warfarin was atrial fibrillation or atrial flutter (n = 38, 55.9%), followed by venous thromboembolism (n = 22, 32.4%). A total of 61 patients (89.7%) had an INR goal range of 2.0-3.0, and the remaining 7 (10.3%) had a goal of 2.5-3.5. Additional baseline demographics and warfarin indications for the study population are presented in Table 1.

For the primary outcome, the difference between the mean TTR in period 1 (Table 2; 69.1% ± 23.2%) and period 2 (69.6% ± 19.2%) was not statistically significant (Table 3; $P = 0.882$). The mean TTR in period 3 (70.5% ± 20.8%) did not differ in statistical significance from either period 1 ($P = 0.688$) or period 2 ($P = 0.746$). Of the secondary outcomes, mean time between visits (in days) during period 2 (30.1 ± 9.6) was statistically significantly greater than that during period 1 (27.0 ± 9.8) and period 3 (27.6 ± 9.4; $P = 0.010$, $P = 0.017$, respectively). The mean number of visits in period 2 (8.1 ± 2.8) was statistically significantly greater than that in period 1 (7.3 ± 3.1; $P = 0.043$) and greater than the mean number of visits in period 3 (7.7 ± 2.7), although this difference was not statistically significant ($P = 0.201$). The

Table 2
Results

Outcome	Mean ± SD
Mean %TTR	
Period 1	69.1% ± 23.2%
Period 2	69.6% ± 19.2%
Period 3	70.5% ± 20.8%
Mean % time in range	
Period 1	65.6% ± 22.6%
Period 2	65.2% ± 18.2%
Period 3	66.0% ± 19.4%
Mean % time out of the range of 1.5–4.5	
Period 1	4.4% ± 9.5%
Period 2	4.9% ± 10.9%
Period 3	4.4% ± 9.0%
Mean time (days) between visits	
Period 1	27.0 ± 9.8
Period 2	30.1 ± 9.6
Period 3	27.6 ± 9.4
Mean number of visits	
Period 1	7.3 ± 3.1
Period 2	8.1 ± 2.8
Period 3	7.7 ± 2.7
Mean % reported adherence to warfarin regimen	
Period 1	85.1% ± 14.3%
Period 2	88.4% ± 11.6%
Period 3	86.7% ± 12.8%
Mean % reported change in diet	
Period 1	23.7% ± 16.2%
Period 2	20.4% ± 14.6%
Period 3	19.6% ± 15.9%
Outcome	n (median % visits with reported event, interquartile range)
Number of reported bleeding events	
Period 1	18 (0.0%, 0.0%–0.0%)
Period 2	15 (0.0%, 0.0%–0.0%)
Period 3	24 (0.0%, 0.0%–11.1%)
Number of ED visits or hospital admissions	
Bleeding	
Period 1	0
Period 2	2
Period 3	3
Thrombosis	
Period 1	1
Period 2	0
Period 3	0

Abbreviations used: ED, emergency department; TTR, time in therapeutic range.
Note: Plus-minus values are mean ± SD.

remaining secondary outcomes of percent TIR, percent of INRs out of the range of 1.5-4.5, percent of visits with patient-reported adherence to warfarin regimen, and percent of visits with a patient-reported change in diet did not differ in statistical significance between any period. There was no statistically significant difference in the percentage of visits with patient-reported or provider-documented minor bleeding events, which were consistently low with a median (interquartile range [IQR]) of 0.0% (0.0%-0.0%) in period 1, 0.0% (0.0%-0.0%) in period 2, and 0.0% (0.0%-11.1%) in period 3. Emergency department visits and hospital admissions for bleeding or thrombotic events were low across all periods and thus were not analyzed.

Discussion

During each period, the average TTR remained in the reported acceptable range for effective anticoagulation at greater than 60%. There was high variation in the average TTR overall in each period, demonstrated by wide standard deviations. This reflects what is seen in clinical practice, given that many factors can affect a patient's TTR such as diet, medication changes, and procedures that require temporary discontinuation of warfarin. A similar conclusion can be drawn from the lack of any statistically significant difference in percent TIR and percent time out of the INR range of 1.5-4.5.

The difference in mean number of visits and mean time between visits in period 2 was statistically significant with approximately 8 visits (compared with approximately 7 in the other periods) and 30 days between visits (compared with 27 and 28). Most patients on stable warfarin therapy are recommended to follow-up for monitoring every 6-12 weeks, whereas patients with a more labile INR require more frequent follow-up to reach a stable regimen.[1] According to AC Forum guidance in 2020, stable patients could have follow-up extended as much as 12 weeks to mitigate exposure to SARS-CoV-2.[5] However, the slight increase in days between visits in period 2 might reflect efforts made to spread out time between visits during the pandemic in accordance with the AC Forum recommendations.[5] This difference in time between visits did not seem to adversely affect TTR, given that there was no difference in TTR between periods. The greater number of visits in period 2 seems to contradict the greater time noted between visits. This observation might be attributed to improved adherence to appointments, but this was not assessed in the study. Several similar studies demonstrated improvement in appointment adherence in drive-up anticoagulation clinics during the pandemic.[11,12,14] However, 1 study in Qatar yielded an increase in no-show rates, which authors suspected may have been attributable to patients' caution to avoid COVID-19.[10]

Bleeding events, as measured by patient- or provider-reported signs and symptoms of bleeding at each visit, were minimal overall; most patients did not have any reported bleeding events in any period, demonstrated by the 0.0% median. The overall low occurrence of reported bleeding events, as well as anticoagulant-related emergency department visits and hospital admissions, could suggest the comparable safety of the drive-up clinic to the traditional clinic model; however, the study was underpowered to detect a difference in these outcomes.

This study had several limitations. We were unable to assess any differences in clinic no-show or cancellation rates in any period because of constraints on the availability of these data throughout the entire study period. Furthermore, the study was not designed to evaluate any direct effects of COVID-19 on anticoagulation, and an evaluation of patients diagnosed of COVID-19 on anticoagulation was beyond the scope of the study. Another limitation is the lack of HAS-BLED scores to evaluate each patient's baseline bleeding risk. The study is also limited by its inclusion of patients who had transportation to attend drive-up clinic appointments, and there may be an undetected effect on adherence given the ease of accessibility for patients who did have reliable transportation. Regarding the logistics of operating the drive-up clinic, the practice did

Table 3
Primary and secondary outcomes

Outcome	Mean difference ± SD (95% CI)	*P* value[a]
Primary end point		
Difference in mean % TTR period 1 vs. period 2	−0.50% ± 27.4% (−7.12% to 6.13%)	0.882
Secondary end points		
Difference in mean % TTR period 2 vs. period 3	−0.92% ± 23.3% (−6.55% to 4.71%)	0.746
Difference in mean % TTR period 1 vs. period 3	−1.41% ± 28.9% (−8.41% to 5.59%)	0.688
Difference in mean % time in range		
Period 1 vs. period 2	0.39% ± 28.6% (−6.54% to 7.32%)	0.911
Period 2 vs. period 3	−0.79% ± 20.5% (−5.74% to 4.17%)	0.752
Period 1 vs. period 3	−0.40% ± 28.4% (−7.27% to 6.48%)	0.909
Mean % time out of the range of 1.5–4.5		
Period 1 vs. period 2	−0.46% ± 11.6% (−3.28% to 2.36%)	0.746
Period 2 vs. period 3	0.52% ± 13.0% (−2.64% to 3.67%)	0.746
Period 1 vs. period 3	0.06% ± 12.7% (−3.01% to 3.12%)	0.971
Mean time (days) between visits		
Period 1 vs. period 2	−3.1 ± 9.7 (−5.4 to −0.7)	0.010
Period 2 vs. period 3	2.6 ± 8.7 (0.5–4.7)	0.017
Period 1 vs. period 3	−0.5 ± 11.6 (−3.3 to 2.3)	0.708
Mean number of visits		
Period 1 vs. period 2	−0.84 ± 3.34 (−1.65 to −0.29)	0.043
Period 2 vs. period 3	0.38 ± 2.44 (−0.21 to 0.97)	0.201
Period 1 vs. period 3	−0.46 ± 3.60 (−1.33 to 0.42)	0.300
Mean % reported adherence to warfarin regimen		
Period 1 vs. period 2	−3.40% ± 17.2% (−7.56% to 0.76%)	0.108
Period 2 vs. period 3	1.79% ± 17.0% (−2.33% to 5.91%)	0.389
Period 1 vs. period 3	−1.61% ± 18.0% (−5.96% to 2.75%)	0.464
Mean % reported change in diet		
Period 1 vs. period 2	3.36% ± 23.2% (−2.26 to 8.97)	0.237
Period 2 vs. period 3	0.76% ± 21.3% (−4.41 to 5.92)	0.771
Period 1 vs. period 3	4.11% ± 20.8% (−0.93 to 9.15)	0.108

Outcome	Median difference ± SE	*P* value[b]
Number of reported bleeding events		
Period 1 vs. period 2	−1.049 ± 43.9	0.294
Period 2 vs. period 3	1.699 ± 43.8	0.089
Period 1 vs period 3	0.331 ± 55.8	0.740

Abbreviation used: TTR, time in therapeutic range.
Note: Plus-minus values are mean ± SD or median ± SE.
[a] Mean differences were calculated using a matched paired-samples *t* test.
[b] Median differences were calculated using a related-samples Wilcoxon signed-rank test.

not make arrangements to operate in extreme weather conditions. This could be considered a limitation of the clinic design in general; however, to implement a drive-up POCT service long term at our institution, the goal is to use a permanent physical structure that would provide protection from extreme weather and limit fluctuations in temperature while still allowing for the patient to remain in their personal vehicle.

One noteworthy consideration regarding this study is the lack of an evaluation of patient satisfaction with the drive-up clinic. Although patient satisfaction was not formally assessed, patients have continued to request the drive-up service. To date, this service has affected UK HealthCare's delivery of anticoagulation management. After the closure of the drive-up model, patients began to request to schedule more in-person visits in the Good Samaritan Medical Office Building, which is more easily accessible to patients with mobility issues because it offers free parking and does not involve a long walk or shuttle ride to the clinic. These results support the exploration of long-term integration of drive-up POCT services including anticoagulation, which may increase patient access to care. The coordination and design of drive-up care models for anticoagulation therapy have been previously described in the literature.[6-18]

One potential application of the drive-up POCT model is in the management of acute and chronic conditions beyond anticoagulation. Previous literature has described the design, benefit, and patient satisfaction of POCT services in the community pharmacy setting.[22-26] These services often include collaborative practice agreements that allow for pharmacist prescribing of medications, such as those to treat positive rapid influenza tests. The goal is to improve ease of access to these tests that, as a traditional delivery model, often require face-to-face clinic appointments depending on the provider or institution.

Conclusions

These results may maintain the feasibility of a drive-up clinic for warfarin management compared with in-person visits. Future studies are warranted to evaluate outcomes on warfarin management and patient satisfaction when implemented on a long-term scale and to evaluate the application of a drive-up model for other POCT services.

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Erin Sherwin, PharmD, PGY2 Ambulatory Care Pharmacy Resident, Graduate Medical Education, University of Kentucky HealthCare, Lexington, KY

Margaret Schaefer, PharmD, PGY2 Ambulatory Care Pharmacy Resident, Graduate Medical Education, University of Kentucky HealthCare, Lexington, KY

Mark Huffmyer, PharmD, BCGP, BCACP, CACP, Pharmacist Manager: Specialty Pharmacy and Infusion Services, Retail Pharmacy Services, University of Kentucky HealthCare, Lexington, KY; and Assistant Adjunct Professor, Pharmacy Practice and Science, University of Kentucky College of Pharmacy, Lexington, KY

Kristina Naseman, PharmD, MPH, BCACP, CDCES, Pharmacist Program Coordinator: Diabetes Stweardship, Pharmacy Services, University of Kentucky HealthCare, Lexington, KY

George A. Davis, PharmD, BCPS, Pharmacist Program Coordinator: Antithrombosis Stewardship, Pharmacy Services, University of Kentucky HealthCare, Lexington, KY; and Adjunct Professor, Pharmacy Practice and Science, University of Kentucky College of Pharmacy, Lexington, KY

Aric Schadler, PhD, Statistician, Kentucky Children's Hospital, Lexington, KY

Savannah Fraley, University of Kentucky College of Pharmacy, Lexington, KY

Brittany Smith, PharmD, BCACP, Clinical Staff Pharmacist, Pharmacy Services, University of Kentucky HealthCare, Lexington, KY

Supplemental Appendix

International Classification of Diseases (ICD-10) codes in data extraction

- Heart failure (congestive heart failure, heart failure with reduced ejection fraction, heart failure with preserved ejection fraction, systolic heart failure, diastolic heart failure)
  - ICD-10: I50.1, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.810, I50.811, I50.812, I50.813, I50.814, I50.82, I50.83, I50.89, I50.9
- Venous thromboembolism
  - ICD-10: I82.0, I82.1, I82.210, I82.211, I82.220, I82.221, I82.290, I82.291, I82.3, I82.401, I82.402, I82.403, I82.409, I82.411, I82.412, I82.413, I82.419, I82.421, I82.422, I82.423, I82.429, I82.431, I82.432, I82.433, I82.439, I82.441, I82.442, I82.443, I82.449, I82.451, I82.452, I82.453, I82.459, I82.461, I82.462, I82.463, I82.469, I82.491, I82.492, I82.493, I82.499, I82.4Y1, I82.4Y2, I82.4Y3, I82.4Y9, I82.4Z1, I82.4Z2, I82.4Z3, I82.4Z9, I82.501, I82.502, I82.503, I82.509, I82.511, I82.512, I82.513, I82.519, I82.521, I82.522, I82.523, I82.529, I82.531, I82.532, I82.533, I82.539, I82.541, I82.542, I82.543, I82.549, I82.551, I82.552, I82.553, I82.559, I82.561, I82.562, I82.563, I82.569, I82.591, I82.592, I82.593, I82.599, I82.5Y1, I82.5Y2, I82.5Y3, I82.5Y9, I82.5Z1, I82.5Z2, I82.5Z3, I82.5Z9, I82.601, I82.602, I82.603, I82.609, I82.611, I82.612, I82.613, I82.619, I82.621, I82.622, I82.623, I82.629, I82.701, I82.702, I82.703, I82.709, I82.711, I82.712, I82.713, I82.719, I82.721, I82.722, I82.723, I82.729, I82.A11, I82.A12, I82.A13, I82.A19, I82.A21, I82.A22, I82.A23, I82.A29, I82.B11, I82.B12, I82.B13, I82.B19, I82.B21, I82.B22, I82.B23, I82.B29, I82.C11, I82.C12, I82.C13, I82.C19, I82.C21, I82.C22, I82.C23, I82.C29, I82.811, I82.812, I82.813, I82.819, I82.890, I82.891, I82.90, I82.91
- LV thrombus (left ventricular thrombus)
  - ICD-10: I23.6, I51.3
- Antiphospholipid syndrome/ antiphospholipid antibody syndrome
  - ICD-10: D68.61
- Lupus/systemic lupus erythematosus/ lupus anticoagulant disorder
  - ICD-10: M32.0, M32.10, M32.11, M32.12, M32.13, M32.14, M32.15, M32.19, M32.8, M32.9
- Protein C Deficiency
  - ICD-10: D68.59
- Protein S deficiency
  - ICD-10: D68.59
- Factor V Leiden
  - ICD-10: D68.51
- Hemophilia A/ Factor VIII Deficiency
  - ICD-10: D66
- Factor II deficiency
  - ICD-10: D68.2
- Antithrombin deficiency
  - ICD-10: D68.59
- Prothrombin Gene Mutation
  - ICD-10: D68.52
- Deep Vein Thrombosis
  - I82.4, I82.5, I82.6, I82.7, I82.9, 453.4, 453.5, 453.8
- Pulmonary embolism
  - I26.0, I26.9, I74.9, 415.1
- Cancer
  - 1.4, 1.5, 1.6, 1.7, 1.0, 2.0, 2.1, 2.3
  - C
  - D.0. D.1, D.3, D.4
- Obesity
  - E66.9
- Stroke
  - I63
- Type 1 diabetes
  - E10
- Type 2 diabetes
  - E11
- Vascular disease
  - 4.1. 4.2
  - I.2, I.3, I.4, I.5
- Hypertension
  - 401
  - I1.0, I1.1, I1.2, I1.3, I1.5, I1.6
- Prosthetic/mechanical valve
  - Z95.2
- Pulmonary hypertension
  - I27.2
- Atrial fibrillation/atrial flutter
  - I48.0, I48.1, I48.2, I48.3, I48.4, I48.9
- CANCER
  - ^1[45679] (this would relate to ICD 10 - 14X.XX, 15X.XX, etc.)
  - ^2[013] (this would relate to ICD 10 - 20X.XX, etc.)
  - ^C (this would relate to ICD 10 - CX.XX, etc.)
  - ^D[0134]
- DIABETES_I
  - ^250\.\d{1}[13]
  - ^E10
- DIABETES_II
  - ^250\.\d{1}[02]
  - ^E11
- HEART_DIS
  - ^4[12]
  - ^I[2345]
  - ^I[23]
- STROKE
  - ^434\.[019]
  - ^I63
- OBESITY
  - ^278
  - ^E66\.9
- HYPERTENSIVE
  - ^401
  - ^I1[012356]

REDCap® Data Collection Form

Patient number:
Appointment date (mm/dd/yyyy):
Goal INR range:
Warfarin indication:
Warfarin ICD10 Code:
Drug-drug interaction identified? (yes/no)
Patient reports missed dose(s)? (yes/no)
Patient reports extra dose(s)? (yes/no)
Patient reports different dose/regimen other than that directed by anticoagulation provider? (yes/no)
Patient reports an upcoming or recent procedure (e.g., colonoscopy, dental work)? (yes/no)
Patient reports change in diet or vitamin K intake? (yes/no)
Patient reports or provider documents bleeding event? (yes/no)
If yes: Bleeding event reported: Gastrointestinal bleed, intracranial hemorrhage, bruising, nosebleed, hematuria, melena, or other (list below)